Workshop 2: Post-IOM Voluntary Counseling and Testing Guidelines and Re-authorization of the Ryan White Care Act

Moderator: Eva Margolies-Seiler

RWCA Re-authorization

Kristin Braun of the AIDS Alliance for Children, Youth & Families and Laura Hanen of the National Alliance of State and Territorial AIDS Directors described the provisions of the Ryan White Care Act Amendments of 2000 and subsequent responses and developments. The re-authorization included provisions for counseling and testing of pregnant women and added treatment services for these women.

Of the $4 million in new funds appropriated, $2 million is reserved for a) states with laws or regulations requiring testing of newborns, and b) two additional states demonstrating the greatest reduction in incidence of perinatal HIV (as determined by CDC). The other $2 million is to be distributed among states falling into the seven criteria outlined in the legislation, very likely to be the existing grantees. This $4 million was appropriated for this fiscal year only.

The Act also requests the Institute of Medicine (IOM) to conduct an evaluation of current perinatal prevention efforts and results to: a) determine the number of infants with HIV born to mothers of unknown HIV status; b) determine the barriers to testing of pregnant women; and c) make recommendations to states on how perinatal transmission can be further reduced. DHHS is to report to Congress on the progress made by the states. Under provisions of the ACT, IOM was given the option of declining this task. They have done so and the Inspector General's office of DHHS will do the evaluation instead.

Two states (Indiana and Kentucky) are currently considering mandatory testing laws.

The proposed new Public Health Service (PHS) recommendations for HIV screening of pregnant women simplify the counseling and consent process for pregnant women. However, some state laws impose stricter requirements on providers than the PHS recommendations.

It is expected that there will be continued Congressional interest in perinatal HIV prevention.

New York State

Roberta Glaros of the New York State Department of Health's AIDS Institute discussed the legislative history of HIV testing of newborns in New York from the early 1980's to 1999. Current program requirements (established in 1999) include mandatory counseling of women in prenatal care and voluntary expedited testing of women presenting for delivery whose HIV status is unknown. If the mother does not consent to testing, her newborn is tested without consent immediately after birth. Expedited testing in labor and delivery setting allows for the administration of partial antiretroviral regimens to reduce perinatal transmission. Since these requirements were put in place, they have seen an increase in testing of pregnant women in the prenatal care setting. Now, ninety percent of pregnant women have been tested prior to their entrance to the hospital. An additional eight percent receive expedited testing in the labor and delivery setting. The remaining two percent are tested through the

Department of Health's Newborn Screening Program.

A study of 631 HIV-positive women delivering in New York State from October 1, 1999 to June 30, 2000 demonstrates the effectiveness of the expedited testing policy. The study found that 72 HIV-positive women presenting for delivery (11 percent) had no history of HIV testing and did not know their HIV status. Expedited testing in the labor and delivery setting was completed on 54 of the these women, allowing for the administrative of partial antiretroviral regimens.

California

Toni Frederick presented. Since 1995, recommendations in Los Angeles County have been that all prenatal patients receive voluntary HIV counseling and testing. It has been mandated by law since 1996.

Data from the Pediatric Spectrum of Disease study from 1995-2000 were analyzed to determine why failures in prevention of perinatal HIV still occurred. Of 608 children born to HIV-infected mothers in the study, 10% were infected with HIV. Twenty percent of the mothers received no prenatal care; 13% were injection drug users. All three antiretroviral interventions (prenatal ZDV, ZDV during labor and delivery and neonatal ZDV) were administered to 67% of the mother-infant pairs. Seventy-four percent of the mothers received ZDV during pregnancy and 86% of infants received neonatal ZDV. As use of maternal ZDV increased over the period, rates of perinatal transmission declined. Prenatal care was highly correlated with intervention with ZDV.

Of the 11 HIV-infected infants born between 1998 and 2000 who received care in Los Angeles County, 6 of the mothers received prenatal care. Two of the infected infants were born to women who received ZDV prenatally and at labor and delivery; these cases represent treatment failure.

To evaluate whether prenatal HIV counseling and testing were being universally offered in the county, the Los Angeles County Department of Health Services interviewed pregnant women after prenatal visits at public and private clinics in the county between June 2000 and January 2001.

Of those surveyed, 95% had received information about HIV and pregnancy, about one-half had received information about HIV treatment and pregnancy, and 99% had been offered an HIV test. A total of 92% accepted the test; the main reasons for refusal were that the woman had already been tested or was in a monogamous relationship. Younger women (13-19 years) were less likely to accept HIV testing than women 20 years of age or older, although the difference was not statistically significant. Foreign-born women were less likely to accept HIV testing than U.S.-born women, but again, statistical significance was not reached. The results confirmed that, to ensure high test-acceptance rates, HIV information and counseling must be an integral component of prenatal care.

On the basis of this survey and other surveys done in Los Angeles County, the following gaps in prevention of perinatal transmission were identified. For those women with prenatal care, 5%-15% were not offered testing; 8%-20% did not accept testing; others were not retested later in pregnancy; and some delivered at a different hospital (i.e., not the HIV referral hospital) where there was either no hospital policy to ask about an HIV test or AZT was unavailable. For those women with no prenatal care (7%-20% among the HIV-infected), the problem is that rapid testing of HIV infection is currently not done.

If implemented as expected, non-named (unique identifier) reporting in California will pose several

challenges: a) duplication of reports within a health department (lab reports and clinician reports); b) duplication of records within the state and outside the state (patient moving, multiple sources of care); c) educating providers (monitoring of their performance, accuracy of reports); d) problems with the unique identifier itself (changing last names, errors in dates, using “0000" for social security number); e) coordination with the PSD study (creating the unique identifier, clarifying reporting roles); f) matching babies and moms (coordination with enhanced perinatal surveillance); and g) how to address exposed babies (assign unique identifier or hold in the PSD database until infection status is determined).

Connecticut

Brian Forsyth from the Yale University School of Medicine commented on the effects of the Connecticut law that provides for mandatory HIV testing of all pregnant women. The law stipulates routine testing at the beginning of pregnancy and again at 26-28 weeks. If prenatal testing is not done, it is to be offered during labor and to the newborn. The law has been effective in increasing testing in pregnant women fourfold.

He compared the percentage of women tested in the pre-law period and 3 months and 9 months after the effective date of the law. There was an increase from 20% to 86% to 95%. Nine months after implementation of the law, testing in higher risk women increased from 40% to 70% to 80%. Perinatal testing in the post-law period for women who did not have a prenatal test was administered to 62% of high-risk women and 27% of women not at high risk. Now, just 8.8% of women identified with higher risk remain untested prior to delivery. It would appear that the requirement for hospitals to offer perinatal testing to women of unknown HIV-status at time of delivery has driven the large increase in prenatal testing. One remaining barrier is the lack of a rapid test in some smaller hospitals since the “expedited” ELISA test is difficult for these hospitals to arrange.